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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,613	01/03/2002	Y Tom Tang	PF-0711 USN	8308

7590 07/10/2003

Incyte Genomics Inc
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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	4

DATE MAILED: 07/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,613	TANG ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-28 are pending in the application.

[2] The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Lack of Unity

[3] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Groups I and II, claims 1, 2, 9, and 16-18, drawn to the special technical feature of an isolated polypeptide, the first claimed method of making, i.e., a method of making a polypeptide, a pharmaceutical composition comprising a polypeptide, and the first claimed method of use, a method of using a composition comprising a polypeptide for treating a disease associated with decreased expression of DETX by administering a composition comprising a polypeptide. Group I recites SEQ ID NO:1 and Group II recites SEQ ID NO:2.

Groups III and IV, claims 3-7, 11, and 12, drawn to the special technical feature of an isolated polynucleotide, a recombinant polynucleotide, and a cell. Group III recites SEQ ID NO:3 and a nucleic acid encoding SEQ ID NO:1 and Group IV recites SEQ ID NO:4 and a nucleic acid encoding SEQ ID NO:2.

Groups V and VI, claim 8, drawn to the special technical feature of a transgenic organism. Group V recites a nucleic acid encoding SEQ ID NO:1 and Group VI recites a nucleic acid encoding SEQ ID NO:2.

Groups VII and VIII, claim 10, drawn to the special technical feature of an antibody that binds a polypeptide. Group VII recites an antibody that binds SEQ ID NO:1 and Group VIII recites an antibody that binds SEQ ID NO:2.

Groups IX and X, claims 19, 20, 25, and 26 drawn to the special technical feature of a pharmaceutical composition comprising an agonist compound and the first claimed method of use, i.e., a method for screening a compound for effectiveness as an agonist, in binding, or as a modulator of a polypeptide. Group IX recites an agonist of SEQ ID NO:1 and Group X recites an agonist of SEQ ID NO:2.

Groups XI and XII, claims 22, 23, 25, and 26 drawn to the special technical feature of a composition comprising an antagonist compound and the first claimed method of use, i.e., a method for screening a compound for effectiveness as an antagonist, in binding, or as a modulator of a polypeptide. Group XI recites an antagonist of SEQ ID NO:1 and Group XII recites an antagonist of SEQ ID NO:2.

Groups XIII and XIV, claims 13-15, drawn to the special technical feature of a method of detecting a target polynucleotide in a sample. Group XIII recites SEQ ID NO:3 and Group XIV recites SEQ ID NO:4.

Groups XV and XVI, claim 21, drawn to the special technical feature of a method for treating a disease associated with decreased expression of DETX by administering a composition comprising an agonist of a polypeptide. Group XV recites an agonist of SEQ ID NO:1 and Group XVI recites an agonist of SEQ ID NO:2.

Groups XVII and XVIII, claim 24, drawn to the special technical feature of a method for treating a disease associated with overexpression of DETX by administering a composition comprising an antagonist of a polypeptide. Group XVII recites SEQ ID NO:1 and Group XVIII recites SEQ ID NO:2.

Groups XIX and XX, claim 27, drawn to the special technical feature of a method of screening a compound for effectiveness in altering expression of a polynucleotide. Group XIX recites SEQ ID NO:3 and Group XX recites SEQ ID NO:4.

Groups XXI and XXII, claim 28, drawn to the special technical feature of a method of assessing toxicity of a test compound. Group XXI recites SEQ ID NO:3 and Group XXII recites SEQ ID NO:4.

[4] The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the polypeptides of Groups I and II, the polynucleotides of Groups III and IV, the transgenic organisms of Groups V and VI, the antibodies of Groups VII and VIII, the agonists of Groups IX and X, and the antagonist of Groups XI and XII share a common property or activity, the compounds are not regarded as being of similar nature because all the alternatives do not share a common structure and thus the molecules share no special technical feature.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acids of Groups III and IV, the

polypeptides of Groups I and II, the transgenic organisms of Groups V and VI, the antibodies of Groups VII and VIII, the agonists of Groups IX and X, and the antagonist of Groups XI and XII share no special technical feature as the nucleic acids of Groups III and IV, particularly the nucleic acids of claim 12, are not required for the polypeptides of Groups I and II as the nucleic acid of Groups III and IV, particularly the nucleic acid of claim 12 encompasses nucleic acids that would not be useful for generating the transgenic organism of Groups V and VI and do not encode the polypeptides of Groups I and II and instead encode polypeptides that would not elicit the antibodies of Groups VII and VIII and would not be agonized or antagonized by the agonists of Groups IX and X or the antagonists of Groups XI and XII.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions of Groups I-XXII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I and II is a polypeptide and the technical feature of Groups III and IV is a polynucleotide, which are shown by Miyazaki et al. (*J Biol Chem* 271:14567-14571; cited in the International Search Report) to lack novelty or inventive step because Miyazaki et al. teach a polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO:3 encoding a polypeptide that comprises an immunogenic fragment of SEQ ID NO:1 and does not make it a contribution over the prior art.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The special technical features of Groups I-XII are not shared by Groups XIII-XXII as 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

[5] Claims 1-28 will be examined only to the extent the claims read on the elected subject matter.

[6] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[7] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner

07/09/03